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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/071,751	02/07/2002	Shirley Wu Hunter	2618-17-C4-PUS-2	2578

22442 7590 06/08/2005

SHERIDAN ROSS PC  
1560 BROADWAY  
SUITE 1200  
DENVER, CO 80202

EXAMINER

STEADMAN, DAVID J

ART UNIT

PAPER NUMBER

1652

DATE MAILED: 06/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/071,751

Applicant(s)

HUNTER ET AL.

Examiner

David J. Steadman

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 69-75 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 71 is/are allowed.
- 6) ☒ Claim(s) 69,70 and 72-75 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: Appendices A, B, and C.

## **DETAILED ACTION**

### ***Status of the Application***

[1] In view of the new rejection set forth below, the finality of the last Office action is withdrawn.

[2] Claims 69-75 are pending in the application.

[3] Applicants' amendment to the claims, filed 4/15/2005, is acknowledged and has been entered into the application. This listing of the claims replaces all prior versions and listings of the claims.

[4] Applicants' arguments filed 4/15/2005 have been fully considered and are deemed to be persuasive to overcome some of the rejections and/or objections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

[5] The text of those sections of Title 35 U.S. Code not included in the instant action can be found in a prior Office action.

### ***Priority***

[6] As noted in a previous Office action, applicants claim priority to US non-provisional application 09/171,156 and international application PCT/US97/05959. While the sequences of SEQ ID NO:61 and 62 of the instant application are supported by application 09/171,156, the sequences of SEQ ID NO:61 and 62 of the instant application are *not* supported by application PCT/US97/05959 as SEQ ID NO:61 and 62 of application PCT/US97/05959 (pp. 146-147 of WO 97/37676) are not identical to SEQ ID NO:61 and 62 of the

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instant application. See Appendices A and B of the instant Office action. Thus, the effective filing date of the instant application is the filing date of application 09/171,156.

***Claim Rejections - 35 USC § 112, Second Paragraph***

[7] The rejection of claims 65-68, 70, and 75 under 35 U.S.C. 112, second paragraph, (¶ [9] of the Office action mailed 11/15/2004) is withdrawn in view of the amendment to the claims.

***Claim Rejections - 35 USC § 112, First Paragraph***

[8] The written description rejection of claims 65-68 and 70 under 35 U.S.C. 112, first paragraph, (¶ [11] of the Office action mailed 11/15/2004) is withdrawn in view of the amendment to the claims.

[9] The scope of enablement rejection of claims 65-68 and 70 under 35 U.S.C. 112, first paragraph, (¶ [12] of the Office action mailed 11/15/2004) is withdrawn in view of the amendment to the claims.

[10] Based upon applicants' failure to show support for the new limitation presented in claim 75 of the response filed 2/17/2005, the examiner noted that the claim raised the issue of new matter in the Advisory action mailed 3/30/2005. In the instant response, applicants provide an additional showing of support for claim 75. In view of this additional showing of support, the examiner agrees that the polypeptide fragment of claim 75 is supported by the specification. The specification discloses that the minimal size of an ectoparasite saliva protein can

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be "about 6 amino acids in length" (see p. 13, lines 21-23 and p. 15, lines 19-22).

The specification discloses that "an ectoparasite saliva protein of the present invention can induce a hypersensitive response" (sentence bridging pp. 42-43), defines hypersensitivity as "a state of altered reactivity in which an animal, having been previously exposed to a compound, exhibits an allergic response to the compound" (p. 1, lines 1416), and describes hypersensitive responses as including immediate and delayed-type hypersensitivity (p. 1, lines 17-18).

### ***Claim Rejections – Double Patenting***

[11] The obviousness-type double patenting rejection of claim 70 as being unpatentable over claims 1-2 of US Patent 5,795,862 (§ [16] of the Office action mailed 11/15/2004), the obviousness-type double patenting rejection of claims 65 and 70 as being unpatentable over claims 1 and 4 of US Patent 5,646,115 (§ [17] of the Office action mailed 11/15/2004), and the obviousness-type double patenting rejection of claim 70 as being unpatentable over claims 14 and 20-21 of US non-provisional application 10/271,344 (§ [18] of the Office action mailed 11/15/2004) are withdrawn in view of the amendment to the claims.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

**[12]** The rejection of claims 65-67 and 70 under 35 U.S.C. 102(b) as being anticipated by GenPept Accession Number S15004 (¶ [15] of the Office action mailed 11/15/2004) is withdrawn in view of the amendment to the claims.

**[13]** The indicated allowability of claims 72-74 is withdrawn in view of the newly discovered reference(s) cited below. Rejections based on the newly cited reference(s) follow.

**[14]** Claim(s) 69-70 and 72-75 are rejected under 35 U.S.C. 102(a) as being anticipated by Frank et al. ("Advances in Veterinary Dermatology Volume 3," Butterworth-Heinemann Medical, Oxford, 1998, pp. 201-212). Claim 69 is drawn to a polypeptide comprising SEQ ID NO:62 that can elicit an immune response to a protein having the sequence of SEQ ID NO:62. Claim 70 is drawn to a composition comprising the protein of claim 69. Claims 72-75 are drawn to a fragment of at least 6 amino acids of SEQ ID NO:62.

Frank et al. teach the isolation of a polypeptide, FS-I, from flea saliva (pp. 205-206 and 208-209). The N-terminus of FS-I (p. 207, top) has 3 additional amino acids relative to SEQ ID NO:62, but otherwise the sequence of FS-I appears to be identical to SEQ ID NO:62 (p. 208). Frank et al. teach the translation of a partial cDNA, which encodes FS-I beginning at the fifth amino acid (p. 209). Frank et al. teach that dogs previously exposed to FS-I exhibited an immune response (p. 209, bottom). This anticipates claims 69-70 and 72-75 as written.

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It is noted that, while the reference of Frank et al. teaches a polypeptide comprising SEQ ID NO:62 and a fragment of SEQ ID NO:62, the examiner can find no teaching or suggestion in the reference of Frank et al. for a polypeptide *consisting of* SEQ ID NO:62.

**[15]** Claim(s) 72-75 are rejected under 35 U.S.C. 102(a) as being anticipated by Database GenBank Accession Number U63555 (GI:3805686). The claims are drawn to a fragment of at least 6 amino acids of SEQ ID NO:62.

Database GenBank Accession Number U63555 teaches a fragment of the polypeptide of SEQ ID NO:62 that is at least 6 amino acids in length (shown in boldface in Appendix C). This anticipates claims 72-75 as written.

It is noted that there is no teaching in Database GenBank Accession Number U63555 that the disclosed polypeptide has the ability to elicit an immune response against SEQ ID NO:62, form an immunocomplex with an antibody raised against SEQ ID NO:62, or induce a hypersensitive response to an animal previously exposed to SEQ ID NO:62. However, these characteristics are an inherent feature of the polypeptide disclosed in Database GenBank Accession Number U63555.

### ***Conclusion***

**[16]** Status of the claims:

Claims 69-75 are pending.


Claim 71 appears to be in a condition for allowance.

Claims 69-70 and 72-75 are rejected.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Steadman, whose telephone number is (571) 272-0942. The Examiner can normally be reached Monday-Thursday and on alternate Fridays from 6:30 am to 4:00 pm. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (571) 272-0928. The FAX number for submission of official papers to Group 1600 is (571) 273-8300. Draft or informal FAX communications should be directed to (571) 273-0942. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Art Unit receptionist whose telephone number is (703) 308-0196.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



DAVID J. STEADMAN, PH.D.  
PRIMARY EXAMINER



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**APPENDIX A**

AAT92823

ID AAT92823 standard; DNA; 1007 BP.

XX

AC AAT92823;

XX

DT 14-APR-1998 (first entry)

XX

DE Flea saliva protein fspI nucleic acid nfspI1007.

XX

KW Flea saliva protein; fspI; allergic dermatitis; allergy; therapy;  
KW diagnosis; nfspI1007; ds.

XX

OS Ctenocephalides felis.

XX

FH Key Location/Qualifiers

FT CDS 1. .468

FT /\*tag= a

XX

PN W09737676-A1.

XX

PD 16-OCT-1997.

XX

PF 10-APR-1997; 97WO-US005959.

XX

PR 10-APR-1996; 96US-00630822.

XX

PA (HESK-) HESKA CORP.

XX

PI Hunter SW, Sim G, Weber ER;

XX

DR WPI; 1997-512409/47.

DR P-PSDB; AAW30483.

XX

PT New flea saliva proteins - useful for treating allergic dermatitis and as  
PT diagnostic reagents.

XX

PS Claim 1; Page 146-147; 179pp; English.

XX

CC This nucleic acid, designated nfspI1007, codes for non-full-length flea  
CC saliva protein (FSP) PfspI155 (see AAW30483) that can be used to treat  
CC allergic dermatitis. It can be obtained by PCR amplification (see  
CC AAT92858-59) and PfspI1007 expressed as a fusion protein in E. coli host  
CC cells. The sense and antisense strands of nfspI1007 are claimed. Claimed  
CC FSP nucleic acids (see also AAT92820-27) can be used in the production of  
CC recombinant FSP polypeptides, as probes to isolate or amplify related  
CC sequences, and therapeutically e.g. as antisense, triplex-forming or  
CC ribozyme molecules for inhibiting the expression of ectoparasite saliva  
CC protein genes. Also contemplated is use of the nucleic acids for in vivo  
CC expression of FSP, e.g. where inserted into a viral vector

XX

SQ Sequence 1007 BP; 440 A; 116 C; 147 G; 304 T; 0 U; 0 Other;

## Alignment Scores:

Pred. No.:	8.26e-84	Length:	1007
Score:	882.00	Matches:	154
Percent Similarity:	99.35%	Conservative:	0
Best Local Similarity:	99.35%	Mismatches:	1
Query Match:	99.21%	Indels:	0
DB:	2	Gaps:	0

US-10-071-192-62 (1-155) x AAT92823 (1-1007)

Qy	1	TrpLysValAsnLysLysCysThrSerGlyGlyLysAsnGlnAspArgLysLeuAspGln	20
Db	1	TGGAAAGTTAATAAAAAATGTACATCAGGTGGAAAAAATCAAGATAGAAACTCGATCAA	60
Qy	21	IleIleGlnLysGlyGlnGlnValLysIleGlnAsnIleCysLysLeuIleArgAspLys	40

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[illegible]

## APPENDIX B

Qy 121 TNEDSKCKKHKCKEKRGGNDAGCDGNFCYCRPKNK 155  
 |||  
 Db 121 TNEDSKCKKHKCKEKRGGNDAGCDGNFCYCRPKNK 155

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**APPENDIX C**

CFU63555  
 LOCUS CFU63555 988 bp mRNA linear INV 28-OCT-1998  
 DEFINITION Ctenocephalides felis flea salivary protein FS-I mRNA, partial cds.  
 ACCESSION U63555  
 VERSION U63555.1 GI:3805686  
 KEYWORDS .  
 SOURCE Ctenocephalides felis (cat flea)  
 ORGANISM Ctenocephalides felis  
 Eukaryota; Metazoa; Arthropoda; Hexapoda; Insecta; Pterygota;  
 Neoptera; Endopterygota; Siphonaptera; Pulicidae; Pulicinae;  
 Ctenocephalides.  
 REFERENCE 1 (bases 1 to 988)  
 AUTHORS Frank,G.R., Hunter,S.W., Stiegler,G.L., Wallenfels,L.J. and  
 Kwochka,K.W.  
 TITLE Salivary allergens of Ctenocephalides felis: Collection,  
 purification and evaluation by intradermal skin testing in dogs  
 JOURNAL Adv. Vet. Dermatol. 3, 201-212 (1998)  
 REFERENCE 2 (bases 1 to 988)  
 AUTHORS Frank,G.R., Hunter,S.W. and Stiegler,G.L.  
 TITLE Direct Submission  
 JOURNAL Submitted (10-JUL-1996) Heska Corporation, 1825 Sharp Point Drive,  
 Ft. Collins, CO 80525, USA  
 REFERENCE 3 (bases 1 to 988)  
 AUTHORS Frank,G.R., Hunter,S.W. and Stiegler,G.L.  
 TITLE Direct Submission  
 JOURNAL Submitted (28-OCT-1998) Heska Corporation, 1825 Sharp Point Drive,  
 Ft. Collins, CO 80525, USA  
 REMARK Sequence update by submitter  
 COMMENT On Oct 28, 1998 this sequence version replaced gi:1575480.  
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 /db\_xref="taxon:7515"  
 /tissue\_type="salivary gland"  
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 /product="FS-I"  
 /protein\_id="AAC69105.1"  
 /db\_xref="GI:3805687"  
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 YRQQLAIPNICKLKNSETNEDSKCKKHCKEKCRRGGNDAGCDGNFCYCRPKNK"  
 ORIGIN  
 Alignment Scores:  
 Pred. No.: 2.72e-170 Length: 988  
 Score: 154.00 Matches: 154  
 Percent Similarity: 100.00% Conservative: 0  
 Best Local Similarity: 100.00% Mismatches: 0  
 Query Match: 99.35% Indels: 0  
 DB: 3 Gaps: 0

US-10-071-192-62 (1-155) x CFU63555 (1-988)

QY 2 LysValAsnLysLysCysThrSerGlyGlyLysAsnGlnAspArgLysLeuAspGlnIle 21  
 |||||  
 Db 3 AAAGTTAATAAAAAATGTACATCAGGTGGAATAATCAAGATAGAAAACTCGATCAATA 62  
 QY 22 IleGlnLysGlyGlnGlnValLysIleGlnAsnIleCysLysLeuIleArgAspLysPro 41  
 |||||  
 Db 63 ATTCAAAAAGGCCAACAAAGTTAAATCCAAATATTTGCAAATTAATACGAGATAAACCA 122  
 QY 42 HisThrAsnGlnGluLysGluLysCysMetLysPheCysLysLysValCysLysGlyTyr 61  
 |||||

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Db 123 CATACAAATCAAGAGAAAGAAAAATGTATGAAATTTTGCAAAAAAGTTTGCAAAGGTTAT 182

Qy 62 ArgGlyAlaCysAspGlyAsnIleCysTyrCysSerArgProSerAsnLeuGlyProAsp 81  
|||||

Db 183 AGAGGAGCTTGTGATGGCAATATTTGCTACTGCAGCAGGCCAAGTAATTTAGGTCCTGAT 242

Qy 82 TrpLysValSerLysGluCysLysAspProAsnAsnLysAspSerArgProThrGluIle 101  
|||||

Db 243 TGGAAAGTAAGCAAAGAATGCAAAGATCCCAATAACAAAGATTCTCGTCCTACGGAAATA 302

Qy 102 ValProTyrArgGlnGlnLeuAlaIleProAsnIleCysLysLeuLysAsnSerGluThr 121  
|||||

Db 303 GTTCCATATCGACAACAATTAGCAATTCCAAATATTTGCAAACTAAAAAATTCAGAGACC 362

Qy 122 AsnGluAspSerLysCysLysLysHisCysLysGluLysCysArgGlyGlyAsnAspAla 141  
|||||

Db 363 AATGAAGATTCCAAATGCAAAAAACATTGCAAAGAAAAATGTCGTGGTGGAAATGATGCT 422

Qy 142 GlyCysAspGlyAsnPheCysTyrCysArgProLysAsnLys 155  
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Db 423 GGATGTGATGGAAACTTTTGTATTGTCGACCAAAAAATATA 464